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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,342	03/01/2004	Lon S. Weiner	M913.12-7	9417
7590 Jeffrey D. Shewchuk Shewchuk IP Services 533 17th Street West Eagan, MN 55121		07/19/2007	EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 07/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,342

Applicant(s)

WEINER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 14, 16, 35 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-13, 15, 17-34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, Species III (claims 1-7, 11-13, 15, 17-34, 36, and 37) in the reply filed on 04/03/2007 is acknowledged.

Claims 8-10, 14, 16, 35 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/03/2007.

Response to Arguments

Applicant's arguments, see remarks filed 11/07/2006, page 6, filed 11/07/2006, with respect to the rejection(s) of claim(s) 28-38 under 35 U.S.C. 102(b) have been fully considered and are persuasive. However, upon further consideration, a new ground(s) of rejection is made in view of the same reference, Huebner (US Pat. 6,030,162).

Applicant's arguments directed toward the remaining claims are not persuasive.

With regard to Applicant's argument that the devices of Huebner relied upon in the rejection cannot be considered to anticipate the claimed invention, the Examiner respectfully disagrees. Though features from different figures were used in the rejection, Huebner repeatedly states that elements from the various devices are interchangeable or adjustable between the various embodiments shown. For example, the tips of any of the screws can be varied (column 5, lines 7-9), the pitch can vary (column 6, lines 22-26), the lengths of different sections of the screws can vary (column 7, lines 39-41), and

the extensions can be placed on any of the screws not just the one embodiment of Fig. 20 (column 8, lines 57-59). Finally, in column 9, lines 40-58, Huebner contemplates combinations of the different embodiments. Therefore, the embodiments of Huebner and the combinations of the embodiments of Huebner can be considered to be anticipatory.

With regard to Applicant's argument that the "non-engaging fragment section" identified in the Office Action is not a section but rather a minor diameter of the screw thread and as such cannot be considered a section, the Examiner respectfully disagrees. The Examiner is not indicating that the non-engaging fragment section is the minor diameter, but is indicating that the non-engaging fragment section is the small portion of the shaft indicated by the line that is located between adjacent threads.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11-13, 15, 17-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (US Pat. 6,030,162).

Huebner discloses a method of repairing a fractured bone comprising advancing a device through a bone fragment, the device having an elongated shaft (top Fig. 22, below) extending about a shaft axis, the device comprising: a bone exterior

section/fragment exterior section (top Fig. 22, below) extending longitudinally about the shaft axis making up at least one third of a total length of the device (top Fig. 22, below); and a bone penetration section (top Fig. 22, below) extending distally from the bone exterior section, the bone penetration section comprising: a non-engaging fragment section extending longitudinally about the shaft axis (top Fig. 22, below); and a bone anchor section (top Fig. 22, below) located distally to the non-engaging fragment section, the bone anchor section having threads for engagement with the anchor bone (top Fig. 22, below), with a major diameter of the threads being greater than a shaft diameter of the non-engaging fragment section (bottom Fig. 22, below); and a compression engagement on a distal end of the bone exterior section (Fig. 21, below), the compression engagement providing a shoulder (Fig. 21 below) extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment; and screwing the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment and with the bone exterior section extending outside the bone, thereby connecting the bone fragment to an anchor bone for a healing duration (Figs. 9 and 10) and extending outside the bone, thereby connecting the bone fragment to an anchor bone for a healing duration and extending out of the bone during the healing duration (column 9, lines 2-6, since the head would protrude from the bone). The bone exterior section is longer than the bone anchor section (top Fig. 22, below). The bone exterior section is more than 45% of a total length of the device (top Fig. 22, below). The bone exterior section has threads of a shallower pitch than the threads of the bone anchor section (top Fig. 22, below), and

wherein the compression engagement is provided by a nut (Fig. 14 below) rotatably supported on the threads of the bone exterior section. The bone exterior section has external threads (Fig. 14 below) which mate with internal threads on the compression engagement (Fig. 14 below), and wherein the inside diameter of the internal threads on the compression engagement is smaller than the non-engaging fragment section such that the internal threads on the compression engagement cannot advance onto the non-engaging fragment section. The bone exterior section has threads of a different thread profile than the threads of the bone anchor section (top Fig. 22, below), and wherein the compression engagement is provided by a nut (Fig. 14 below) rotatably supported on the threads of the bone exterior section. The device is provided in a kit of a plurality of such devices each having a different length of non-engaging fragment section (column 7, lines 36-41). The various embodiments found in the specification (Figs. 15-22) can be considered a kit. The compression engagement has a proximal side with a sloped profile to assist in removing the compression engagement after a healing duration through tissue (Fig. 21 below). A slope of the proximal side of the compression engagement increases from a gentle slope adjacent an outer diameter of the bone exterior section to a steeper slope distal to the gentle slope, thus providing a compression engagement of generally tear-drop cross-sectional shape (Fig. 21, below). The compression engagement is permanently fixed to the bone exterior section (Fig. 21, below). The shaft of the non-engaging fragment section is substantially smooth and cylindrical (top Fig. 22 below). The compression engagement is permanently fixed to the bone exterior section (Fig. 21 below). The threads on the bone anchor section are self-

tapping distally for insertion (top Fig. 22, below). The threads on the bone anchor section are self-tapping proximally for removal (top Fig. 22, below). The compression engagement has a tear drop cross-sectional shape (Fig. 21 below), wherein the compression engagement is permanently affixed to the bone exterior section (Fig. 21 below), wherein the shaft of the non-engaging fragment section is substantially smooth and cylindrical (top Fig. 22, below), and wherein the threads on the bone anchor section are self-tapping distally for insertion (top Fig. 22, below) and self-tapping proximally (top Fig. 22, below) for removal. The bone anchor section ends in a distal drill tip (top Fig. 22, below) adapted for insertion in bone without pre-drilling. The shoulder of the compression engagement has a curvature (top Fig. 22, below) to contact the exterior surface of the bone fragment along the curvature. The fragment exterior major diameter is no greater than a mean of the anchor major diameter and the anchor minor diameter (bottom Fig. 22, below). The fragment major diameter can be made smaller than the average of the anchor major diameter and the anchor minor diameter (column 3, lines 41-43 and column 5, lines 33-41). Huebner further discloses a rotation section (top Fig. 22, below). Huebner further discloses a pointed proximal drill tip (top Fig. 22, below).

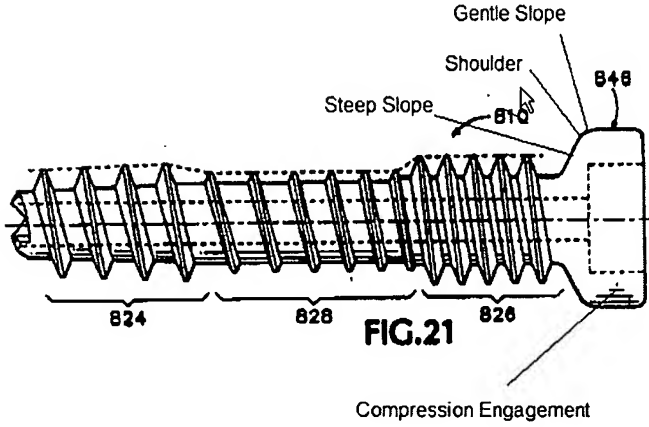
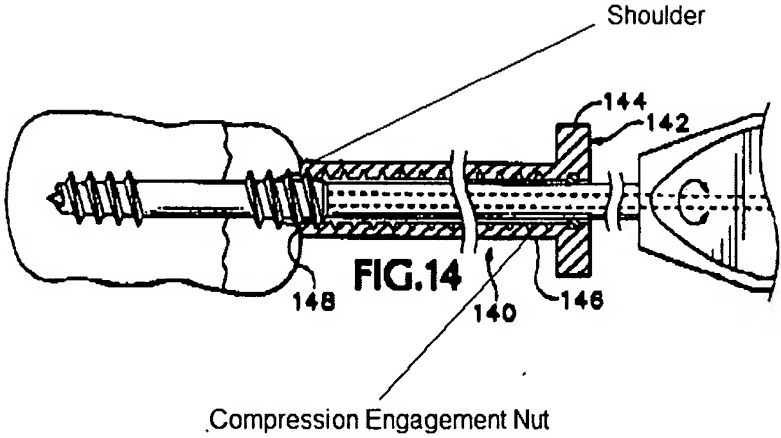
The device of Huebner can perform a method of repairing a fractured bone, comprising: screwing a device through a bone fragment (Fig. 8 and 9), the device comprising (Figs. below): an elongated shaft having a bone penetration section extending distally from a bone exterior section about a shaft axis, the bone penetration section being shorter than the bone exterior section, the bone penetration section including a fragment section and a bone anchor section located distally to the fragment

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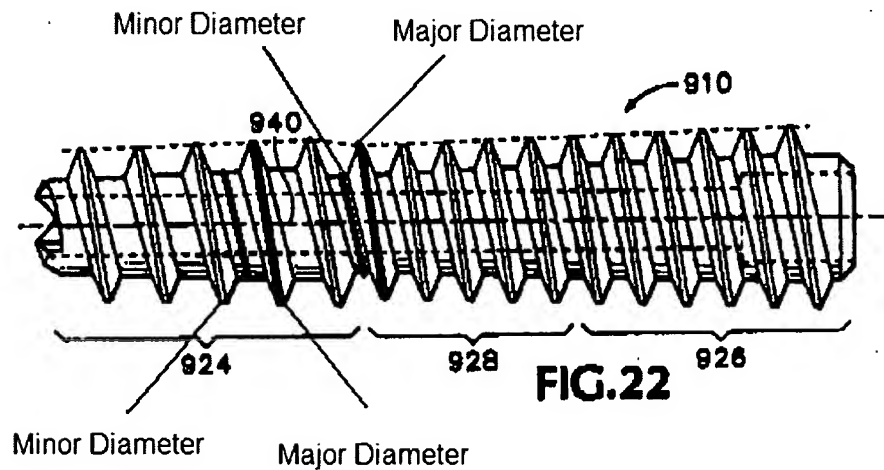
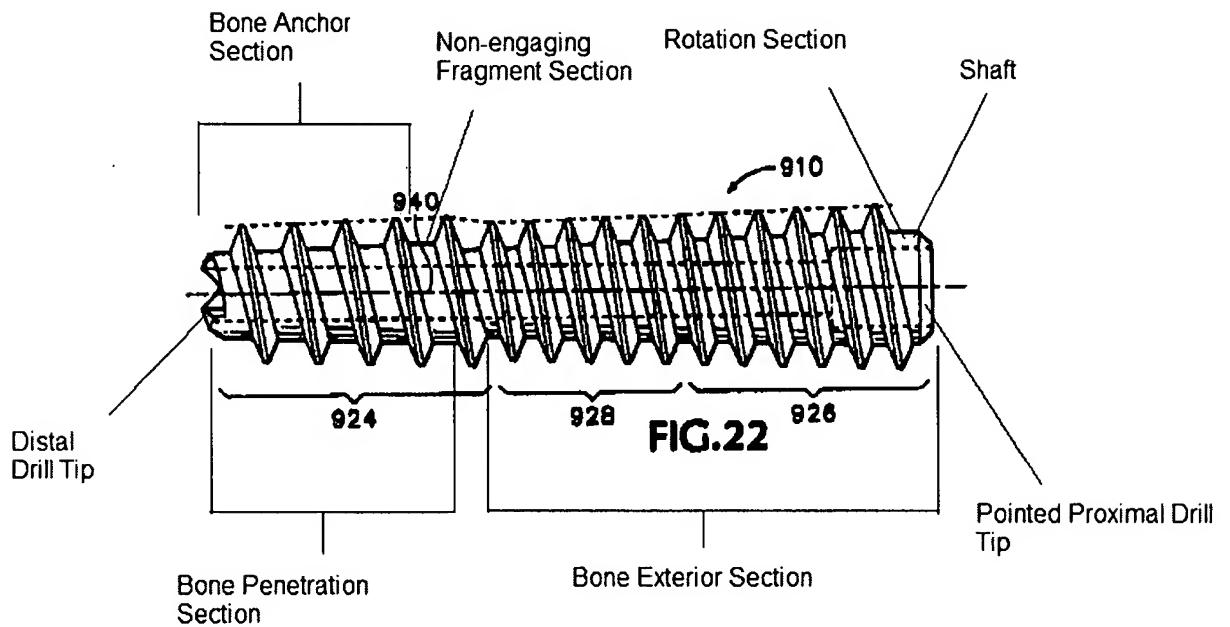
section, the bone anchor section having threads with a major diameter of the threads being greater than a diameter of the fragment section, and a compression engagement on a distal end of the bone exterior section, the compression engagement providing a shoulder extending at a substantial angle to the shaft axis; and further screwing the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment (Fig. 9, since one fragment can be considered to be the anchor bone and one can be considered to be the fragment section). The device of Huebner can further perform a method with the bone anchor section advanced into the bone fragment but prior to the act of further screwing the device into the anchor bone, manipulating the bone exterior section to reposition or bias the bone fragment relative to the anchor bone (column 6, lines 57-62). The device of Huebner can further perform a method including, after the manipulating act, holding the bone exterior section in a desired alignment during the further screwing act (column 6, lines 62-66). After the further screwing act: the fragment section extends through the bone fragment without threaded engagement with the bone fragment; and the threads of the bone anchor section are in engagement with the anchor bone; and the compression engagement is in substantial contact with an exterior surface of the bone fragment to bias the bone fragment toward the anchor bone (Fig. 9) (Fig. 22, below). The device of Huebner can further perform a method including moving the compression engagement axially on the elongated shaft to position the compression engagement in an axial position to make substantial contact with an exterior surface of the bone fragment when the bone anchor section is advanced to a final position (Figs. 8 and 9). The device of Huebner can

further perform a method where the compression engagement has a proximal side with a sloped profile (Figs. 11-14), and further comprising: after a healing duration, removing the compression engagement through tissue with the sloped profile on the proximal side of the compression engagement assisting in separating tissue (since some healing, though minimal, will occur while the compression engagement is being utilized, and the compression engagement will be removed from the body upon emplacement of the compression device). The device of Huebner can further perform a method further comprising monitoring torque applied during the further screwing act (since the torque must be monitored by the surgeon, even if only using tactile indications).

The device of Huebner can further perform a method of using a reverse-taper threaded compression device for placing a compression force on a fragment against an anchor substrate, the method comprising: advancing an anchor section disposed on a distal end of a shaft of the compression device into the anchor substrate (Figs. 9 and 10), such that external threads on the anchor section engage the anchor substrate (Figs. 9 and 10); advancing a compression engagement (Fig. 14, e.g. ref. 146) disposed on a fragment exterior section proximal to the anchor section relative to the shaft, such that the compression engagement makes contact with an exterior surface of the fragment to bias the fragment toward the anchor substrate (Figs. 9 and 10).



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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (US Pat. 6,030,162) in view of Taras et al. (US Pub. 2003/0158556 A1).

Huebner discloses the claimed invention except for cutting off a portion of the fragment exterior section, the cut preventing the compression engagement from axially retracting on the shaft.

Taras et al. disclose a method of using a fracture fixation device (Fig. 1, ref. 10) including a step of cutting off a portion of the shaft (paragraph 0033) in order to create a flush connection (paragraph 0033).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Huebner with the step of cutting off a portion of the shaft as taught by Taras et al., in order to create a flush connection (paragraph 0033).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)*, *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)*, *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982), *In*

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re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970)*, and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-19, 21-23, and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5, 7-11, 14, 22, 24, 28, 29 of copending application # 10/300,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 1-2, 4-19, 21-23, and 29 of the application and claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078 lies in the fact that the application # 10/300,078 claims include many more elements and are thus much more specific. Thus the invention of claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078 is in effect a "species" of the "generic" invention of claims 1-2, 4-19, 21-23, and 29. It has been held that the generic invention is "anticipated" by the "species". See In re Goodman, 20 USPQ2d 2010 (Fed. Circ.1993). Since claims 1-2, 4-19, 21-23, and 29 are anticipated by claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078, they are not patentably distinct from claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

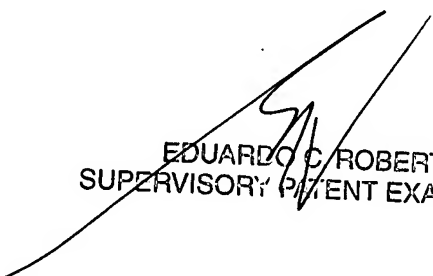
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER